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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,340	12/04/2003	Dirk Jager	LUD-5793.1 CIP	3224
24972 7590 03/09/2007 FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			EXAMINER HALVORSON, MARK	
			ART UNIT	PAPER NUMBER
			1642	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/09/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/729,340

Applicant(s)

JAGER ET AL.

Examiner

Mark Halvorson

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13, 58-60, 85, 86, 92 and 115 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 13, 92 is/are allowed.
- 6) ☒ Claim(s) 58-60, 85, 86 is/are rejected.
- 7) ☐ Claim(s) 115 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: search results.

### **DETAILED ACTION**

Claims 13, 58-60, 85, 86, 92 and 115 are pending.

Claims 13, 58-60, 85, 86, 92 and 115 are under currently under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Objection to Specification maintained**

The objection to the specification is maintained. The specification must be amended to reflect that application Serial No: 09/602,362 is now U.S. Patent No:6,911,529 and application Serial No: 09/451,739 is U.S. Patent No: 6,774,226.

### ***- 35 USC § 112 2<sup>nd</sup> paragraph rejection maintained***

The rejection of claim 58 for being indefinite is maintained. Claim 58 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As amended, the phrases "consisting of an amino acid sequence of from 8 to 25 amino acids which are present in consecutive order in the isolated cancer associated antigen" is indefinite because it is not clear what is meant by this phrase. The phrase can be interpreted as having three meanings. The claim reads on a exogenous amino acid sequence inserted into the amino acid sequence of the isolated cancer associated antigen, a peptide fragment of the isolated cancer associated antigen inserted into the isolated cancer associated antigen or a peptide fragment of the isolated cancer associated antigen. For examination purposes the claim is interpreted as reading "a composition comprising at least one MHC binding peptide, the peptide consisting of an amino acid sequence of 8 to 25 amino acids in consecutive order from the isolated cancer associated antigen."

Applicant argues that amended claim 58 has been approved by the USPTO in light of claim 20 of U.S. Patent No. 6,830,924. Applicant's arguments have been fully

Art Unit: 1642

considered but they are not persuasive. First, each patent application is examined on its own merits. Further, the claims of U.S. Patent No. 6,830,924 are not drawn to MHC-binding peptides.

***35 USC § 112 1<sup>st</sup> paragraph rejection maintained***

The rejection of claims 58-60 85 and 86 for failing to comply with the enablement requirement is maintained.

It is noted that, as Applicant stated in the Office Action, the correct peptide size disclosed in Figs. 7.22 and 7.23 of Roitt is 9 amino acids.

Applicants argues that given the finding in U.S. Patent No. 6,830,924 that a claim of this type is enabled, the presumption of enablement for claims 58-60 is even stronger. Applicants further argues that a specification does not need to teach that which the art already knows. Thus, Applicants argue that there is sufficient guidance in the specification to enable a composition comprising at least one MHC binding peptide. In addition, Applicants argue that an application filed three years earlier is not state of the art for the instant application.

Applicant's arguments have been fully considered but they are not persuasive. First, each patent application is examined on its own merits. Further, the claims of U.S. Patent No. 6,830,924 are not drawn to MHC-binding peptides.

The specification does not enable one of ordinary skill in the art to make and use the claimed MHC binding peptides. The specification contemplates the use of the peptides which complex with an MHC molecule to generate cytolytic T cells against cancer cells. (paragraph 003). The specification discloses three peptides that induced presensitized CD8<sup>+</sup> cells to secrete anti-interferon gamma. There is insufficient guidance in the specification to one of ordinary skill in the art to make and use any claimed MHC binding peptide of SEQ ID NO:32 to generate cytotoxic cell against cancer cells. First, the number of potential MHC binding peptides from a peptide consisting of 1397 amino acids is enormous. Second as disclosed by Wang et al finding a peptide that binds to a MHC molecule and stimulates an immune response is not a trivial matter. Finding a peptide that binds to a specific MHC molecule is only the

Art Unit: 1642

first hurdle. The biggest hurdle is using the MHC binding peptide to generate cytolytic T cells against cancer cells.

The rejection of claims 58-60 85 and 86 for failing to comply with the written description requirement is maintained.

Applicants argue that they have defined a representative number of proteins encoded by the corresponding ORF of SEQ ID NO:31 or have recited structural features common to the members of the genus to sufficiently describe the genus of peptide fragments of SEQ ID NO:32.

Applicants further argue that they have identified a function of the claimed peptides; that they are "cancer associated antigens" meaning that they serve as indicators of the presence of cancer.

Applicant's arguments have been fully considered but they are not persuasive. The polypeptide of SEQ ID NO:32 is 1397 amino acids. The number of peptide fragments greater than eight or nine amino acids that could be generated from the polypeptide of SEQ ID NO:32 is enormous. Applicants have demonstrated that three peptide fragments have bound HLA-A2 molecules and stimulated CTL proliferation. Applicants have not defined a sufficient number of representative species to demonstrate that they had possession of the genus of peptide fragments of SEQ ID NO:32. Furthermore, Applicants have not pointed out any structural features in common between the three peptides that could be used to define the genus of peptide fragments claimed in the instant application.

In addition, the genus of cancer associated antigens is enormous with few structural features in common that can be related to a common function. The function discussed in the Office Action refers to a specific function of the peptides or segment of the peptides. The broad function "indicators of the presence of cancer" does not satisfy the structure-function requirement of the written description requirement. Applicants have not pointed out any common structural features within the genus of peptides claimed by Applicants.

## **NEW REJECTION BASED ON AMENDMENT**

### **Claim Objections**

New Claim 115 contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

Three sequences of claim 115 are not identified by a SEQ ID NO. In addition there are sequences on pages 20-21 that do not have SEQ ID NOs.

In response to this office action, Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. The nature of the non-compliance did not preclude an examination of the elected invention on the merits, the results of which are presented below.

### **Summary**

Claims 58-60 85 and 86 stand rejected.

Claim 115 is objected to for lacking SEQ ID NOs.

Claims 13 and 92 appear allowable as the closest prior art is Jiang et al who describe a breast tumor polypeptide that has 96% sequence identity with the peptide of SEQ ID NO:32. (see search results).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD  
Patent Examiner  
571-272-6539

  
SHANON FOLEY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600